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The Introduction of Custom Earplugs aboard LCS-1

by

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NSMRL was responsible for providing custom-molded hearing-protective devices (HPDs) and conducting advanced hearing-conservation efforts with the crew of USS FREEDOM (LCS-1) as part of a longitudinal study on the effectiveness of a hearing-conservation program. This report documents our relevant experience with LCS-1 crewmembers, discusses related reports on the use of foam and custom HPDs, and provides interim recommendations.

Custom-molded HPDs were judged by users to be superior in comfort, and able to be worn for longer periods of time than other devices (foam). Based on data from LCS and other related studies, the performance, acceptance, and cost of the custom-molded product are comparable, or better, than foam HPDs. The interim recommendation is to provide multiple types of HPDs, including custom earplugs, to service members.

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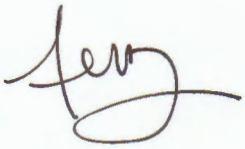

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ABSTRACT

NSMRL was responsible for providing custom-molded hearing-protective devices (HPDs) and conducting advanced hearing-conservation efforts with the crew of USS FREEDOM (LCS-1) as part of a longitudinal study on the effectiveness of a hearing-conservation program. This report documents our relevant experience with LCS-1 crewmembers, discusses related reports on the use of foam and custom HPDs, and provides interim recommendations.

Custom-molded HPDs were judged by users to be superior in comfort, and able to be worn for longer periods of time than other devices (foam). Based on data from LCS and other related studies, the performance, acceptance, and cost of the custom-molded product are comparable, or better, than foam HPDs. The interim recommendation is to provide multiple types of HPDs, including custom earplugs, to service members.

Academic and industry studies confirmed our findings that the amount of sound attenuation provided by dispensed custom earplugs was variable, with some extremely protective results, and occasional very poor performance. High professional qualification (certified audiologist) and manufacturer training were not always sufficient to consistently produce high quality HPD impressions and subsequent custom HPDs, even if they passed a cursory visual inspection.

One of the factors found to affect custom HPD attenuation is canal depth. High attenuation from these devices was shown, in the laboratory, to depend on a critical depth in the ear canal; however, this depth was not consistent across people. It is important for the canal depth to be sufficient for the attenuation needed for each sailor's noise environment, while maintaining enough comfort to be worn. We recommend impression takers and earplug dispensers attend a manufacturer's course, and receive refresher training from someone experienced in deep ear mold impression taking and fitting.

There is no way at present to *a priori* determine how much attenuation will result in an ear from a particular HPD. The interim recommendation is to directly measure hearing-protective-device attenuation as part of any earplug dispensing, whether custom, foam, or flange.

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INTRODUCTION

We studied the impact of custom-molded hearing-protective devices (HPDs) as part of an enhanced hearing-conservation program aboard USS FREEDOM (LCS-1). Custom-molded earplugs ("customs") for hearing protection were issued to crews of a new class of ship, the littoral combat ship (LCS) FREEDOM. In this report, we discuss attenuation, variability of attenuation across repeated insertions into the same ear, effect of training, the importance of comfort and individual preference, and cost. We also compare the custom HPD to the ubiquitous foam HPD in each of these areas. We discuss data from the LCS-1 crew, and selected laboratory studies and industrial studies. This is not intended to be a comprehensive review of all the literature on hearing protectors, but rather observations of custom HPD use onboard one naval vessel. Based on the body of data presented below, recommendations for implementing Navy-wide customs earplugs are made in each section, and are summarized at the end of the report.

Figure 1. Photo of Westone Style #40 silicone custom plug, identical in manufacture to the Westone ACCES High Performance plug issued to LCS-1 crew.

1. Attenuation

The function of HPDs is to attenuate (reduce) the level of sound reaching the eardrum of individuals working in noise-hazardous environments. To test personal attenuation (PAR), real-ear-attenuation-at-threshold (REAT) testing is the "gold standard" measurement. REAT compares hearing thresholds with and without earplugs in an ANSI-certified, laboratory setting. A PAR is calculated from frequency-specific data into a single number given in decibels for each ear. We used a field version of these measurements, a fit-check, one that delivers the sound through headphones to the listeners, rather than the free-field measurements that are the ANSI standard. Fit-check measurements were performed with some of the LCS-1 crew using custom and foam earplugs.

Attenuation data. Data from custom-molded earplugs for members of the LCS-1 crew are shown in Figure 2. Results for foam earplugs are presented later in the section on training (Figure 7). Each symbol in Figure 2 is the measured PAR (expressed in dB) of the Westone High Performance HPD from one ear, after insertion by the user. Measurements were made with the Michael and Associates FitCheck using five frequencies (250, 500, 1000, 2000, and 4000 Hz). Between 2008-2010, deep-canal impressions for the custom-molded earplugs were taken, and the custom earplugs were dispensed (including visual inspection of the fit and training on insertion, acclimatization, and care of the HPD), by military medical personnel or occupational

audiologists. All impressions passed the manufacturers' inspections. The important points from Figure 2 are: 1) most plugs give slightly less attenuation than advertised by the manufacturer (29 dB); 2) a few plugs provide superior attenuation (over 40 dB), making them eligible for use in very high noise environments; and 3) some plugs fail to provide adequate attenuation for the LCS environment (15 dB or below). The category cut-offs are arbitrary and inserted to allow text descriptions. The sources of possible variability are discussed later in this paper.

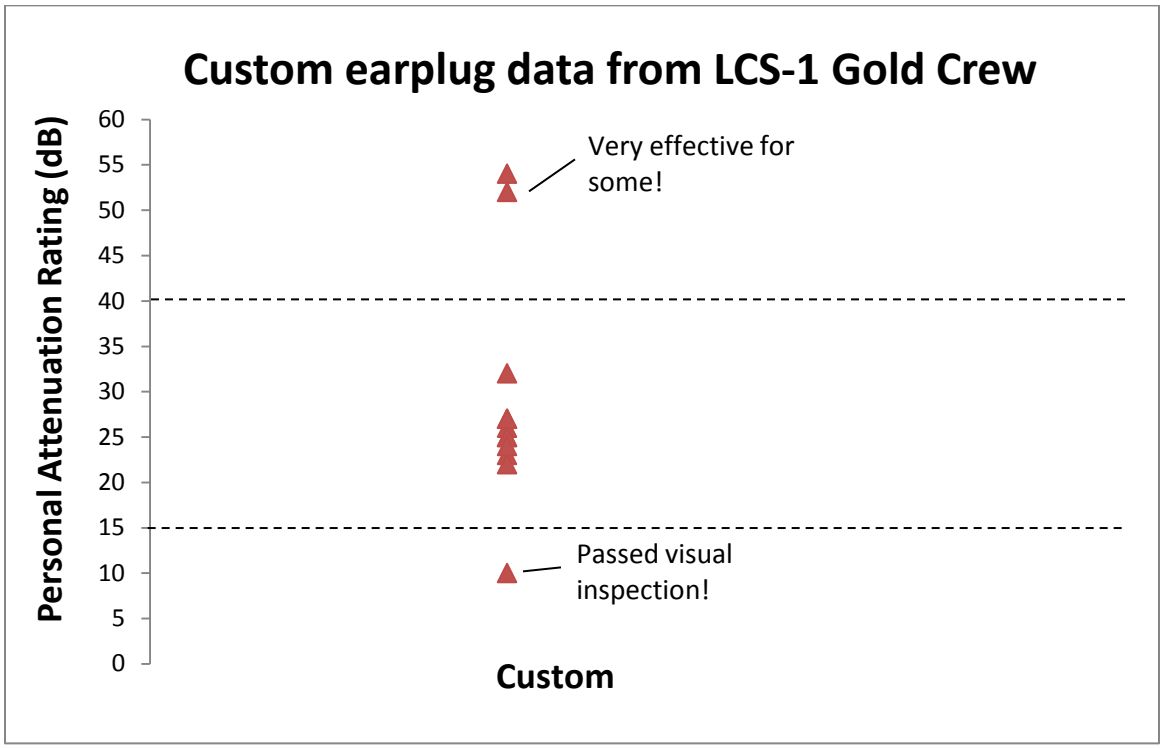

Figure 2. Measured PAR of custom HPDs prepared for the LCS-1 crew. Each symbol represents the measurement of one ear. The dotted horizontal lines separate regions of performance discussed in the text.

Poorly attenuating earplugs create a hazard to the wearer. It became clear from these results that the attenuation of custom HPDs must be measured at the time they are dispensed. This recommendation is true for every type of earplug that is dispensed, as will be discussed later.

Tufts et al. (2012b) measured the PAR of custom HPDs (Figure 3) in a student population. Test subjects were provided minimal training in plug insertion. The custom earplugs (Westone Style #40) were produced at the same manufacturing facility as the LCS HPDs previously mentioned. The measurement technique used was the same Michaels and Associates Fit Check system as used with the LCS crew, and the plugs were inserted by the subjects. Again, three categories of PAR measurements are seen: a majority with attenuation between 15 and 40 dB, a few with even greater performance, and several with worse performance. One of the poorly performing earplugs was noticed later to fit loosely in the subject's ear. The presence of very low attenuation

in several plugs in this study supports the need for verification so that every dispensed earplug has the attenuation needed by that individual.

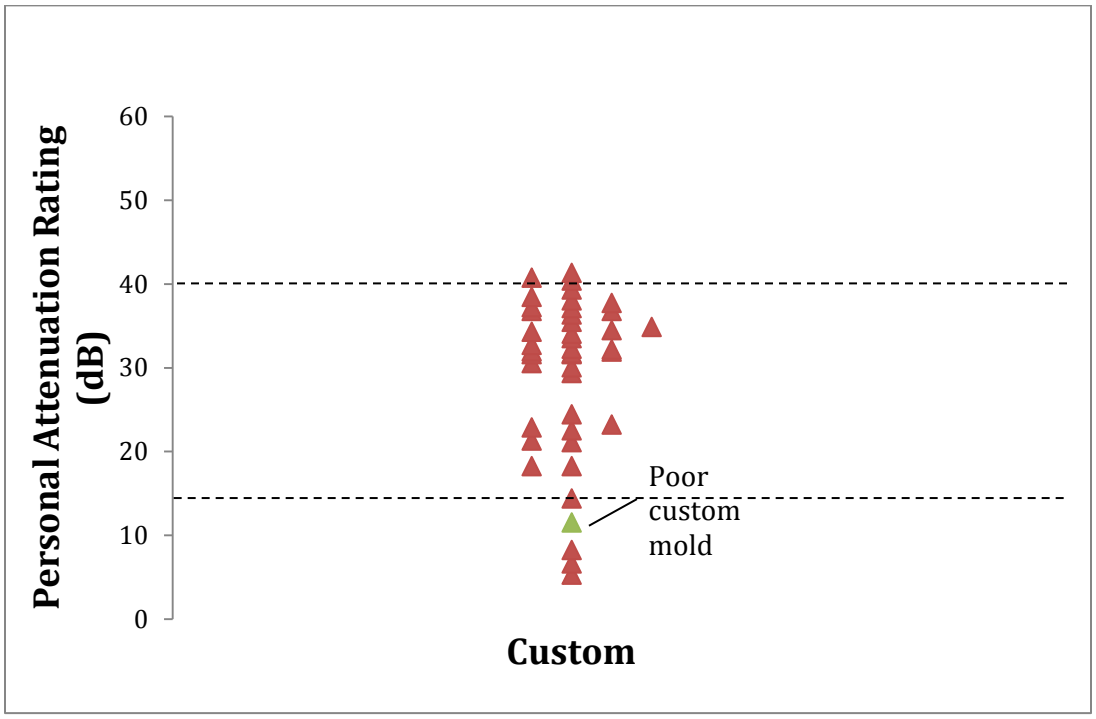

Figure 3. Measured PAR of custom earplugs (Tufts et al. 2012b). Each symbol represents the measurement on a single ear from one person. Symbols are spaced horizontally to avoid substantial overlap. The dotted horizontal lines separate regions of performance discussed in the text.

Depth as a factor of attenuation. Insertion depth of hearing protection has been shown to be a factor in estimated attenuation. A foam earplug inserted 5-9 mm (a quarter of the way) into the canal is estimated to give no attenuation (Bjorn 2006). Impressions for custom HPDs are made to the second bend of the ear canal and are manufactured with several anatomical landmarks to "lock" the earplug into proper position and depth. Several studies from university and industry have focused on the issue of custom earplug depth and attenuation.

Canal depth was the subject of a study at Creare. They used computer modeling to replicate an anatomically correct ear responding to various earplug depths and girths, reporting changes in attenuation. Results were presented as a noise reduction rating (NRR), not a PAR. The NRR is another summary measure of attenuation, defined with different procedural and statistical steps than a PAR. Specific numbers of PAR and NRR cannot be directly compared. Figure 4 shows the depth data, which has a gradual, nearly linear, decrease in attenuation with decreasing insertion depth (Norris et al. 2012). Increasing the thickness of the earplug did not have a significant change in attenuation.

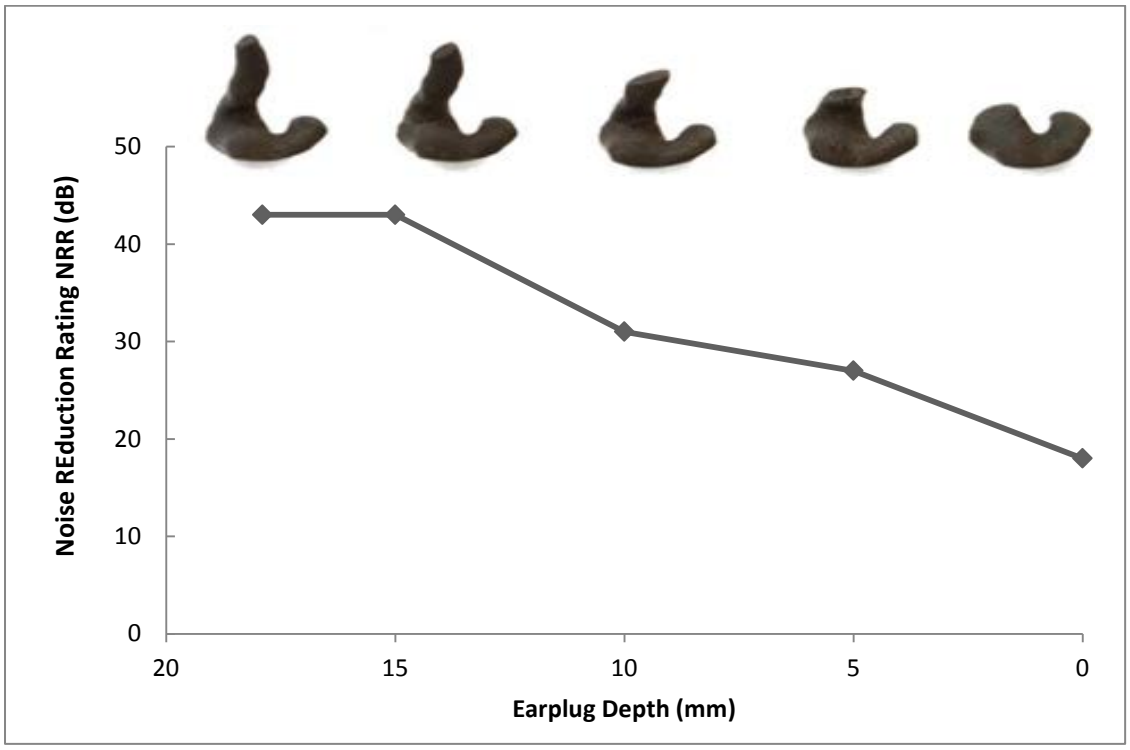

Figure 4. Results of custom earplug depth and attenuation using a computer-simulated anatomical ear (adapted from Norris et al. 2012).

Tufts et al. (2013) also studied the effects of earplug canal depth on sound attenuation and user comfort. Investigators used Westone's ACCES High Performance HPD, the same style dispensed to the LCS crews. The manufacturer was asked to make the plugs as long as the impressions allowed, passing the second bend in the ear canal by 3-4 mm, which is deeper than the custom earplugs manufactured for LCS-1. On subsequent days, the plug's canal length was

shortened, and both attenuation and comfort were assessed. One individual's results from that study are displayed in Figure 5. The maximal attenuation is over 40 dB. Above 25 dB attenuation is provided if the plug insertion depth is at least 11 mm, but performance drops off sharply for a shallower earplug. However, note that the lower attenuation around 15 dB is stable, even as the earplug was shortened.

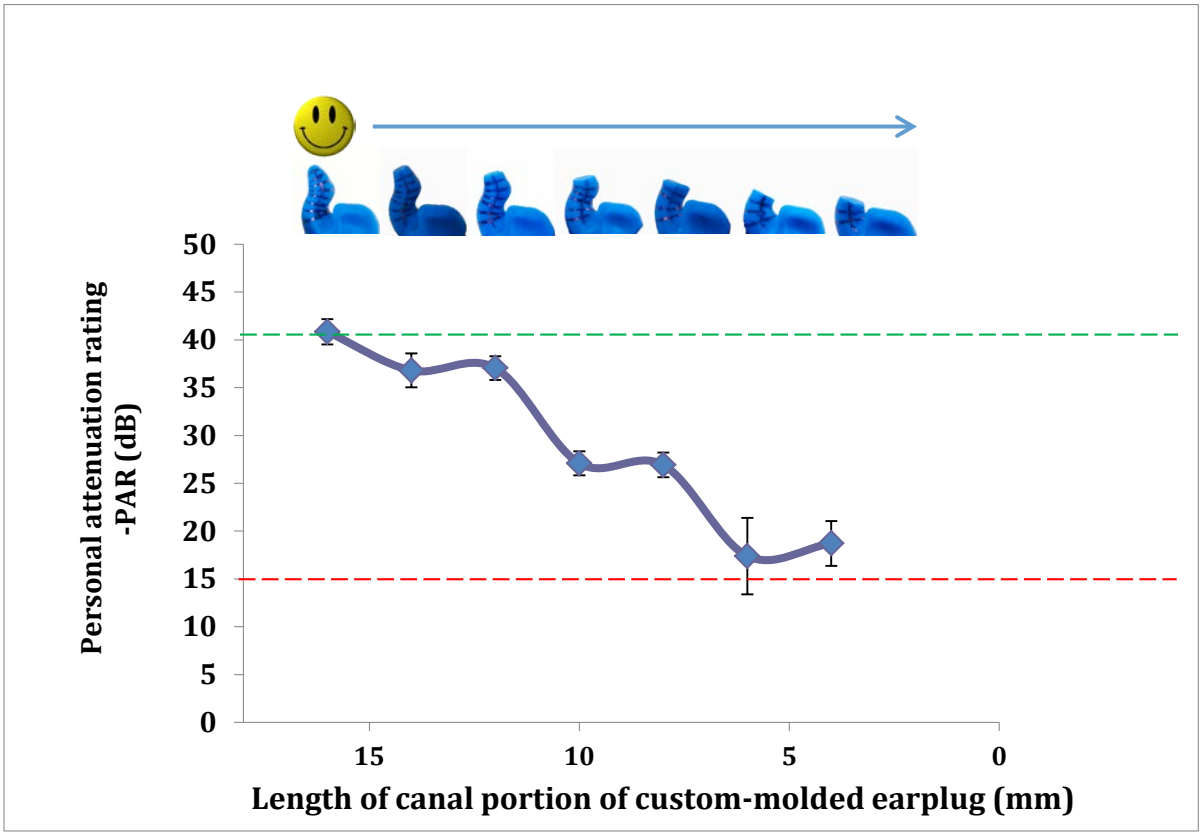

Figure 5. Measured attenuation (expressed as PAR) as a function of HPD canal length. This subject expressed comfort from the beginning of insertion, as indicated by the smiley face above the first earplug. Pictures below the face are of the progressive cuts made to make the earplug shallower in the canal. (adapted from Tufts et al. 2013).

Three other individuals were studied in the same manner (see Figure 6). Each individual had different critical depths for good attenuation or a gradual change over the insertion depth. These results are further evidence for the need of individual fit-check testing.

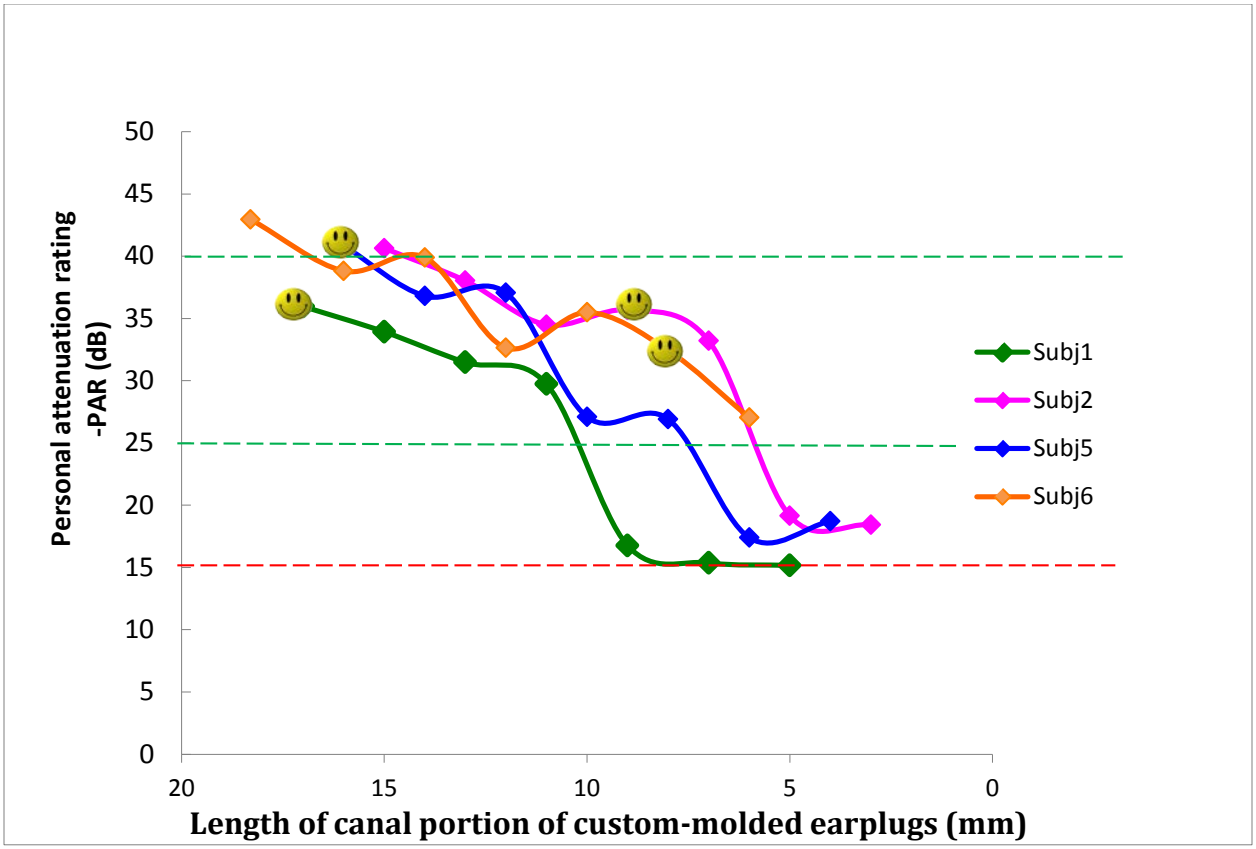

Figure 6. Measured attenuation (expressed as PAR) as a function of canal depth for all subjects. Smiley faces are the deepest depth where the subjects reported comfort as will be discussed later in the text (adapted from Tufts et al. 2013).

Results from three of four subjects show that there is a critical region in custom plugs that provides both good attenuation and comfort. The critical depth in this group of subjects was either between the first and second bend in the ear canal, or near the second bend itself. This study highlights the importance of a "deep enough" custom earplug, meaning that most of the possible protection has been achieved by the critical depth. This also shows that the attenuation can be "tuned" (by adjusting the canal depth) to the work environment, with greater attenuation for noisy environments and less attenuation for less noisy environments. As will be mentioned later, this "tuning" might also increase comfort, thereby increasing the probability that the HPDs will be worn consistently.

Measuring attenuation in the field. Even with good lab results, a plug can fail in the field if the user inserts them improperly. Aboard several ships, Bjorn et al. (2006) observed that a majority of foam earplugs were visibly out of proper position, with 79% of personnel interviewed receiving an estimated 0-6 dB of attenuation. Other insertion errors may not be as visible. Our recommendation is to verify adequate attenuation of self-inserted earplugs, using an appropriate technique (fit-testing). This must be done separately for each type of HPD.

Fit-testing has been successfully introduced in industry. Recently, an aircraft company reported its experience with HPDs in its factories (Johnson and Calimlim 2012). Concerned about

hearing, the company tested the attenuation achieved by all employees wearing their choice of HPD. Only about half met the company goal of attaining 15 dB of attenuation. Those who fell short completed additional cycles of a process during which they were given opportunities to choose their HPDs, receive further training, and re-test the attenuation. Eventually the company goal was met by all individuals. These results support the addition of fit-testing both in the LCS-1 program and likely Navy-wide as well.

2. Variability of attenuation across repeated insertions into the same ear

There appear to be at least three factors responsible for variability in the custom HPD attenuation. The first is improper insertion which may allow sound to leak around the HPD and into the ear canal. This phenomenon can also occur due to poor matching of the HPD to the user's anatomy commonly caused by poor earmold impression taking or manufacture. Visually inspecting and handling the HPD while in the user's ear can show that the fit is not snug, but these are not fool-proof indicators of a poor fit. The second factor, also associated with fit, is inadequate training of the individual inserting his/her own HPD. (Training is discussed further below). Users should be instructed to correctly "seat" the custom HPD so that it "locks" into the helix and concha of the ear. The third factor is depth of the canal portion of the HPD. In general, deeper canal lengths result in greater attenuation, but the attenuation at each depth varies across individuals.

A report that average attenuation is good does not guarantee good individual performance. A collection of well-attenuating earplugs (on average) will still have some poorly performing individual earplugs if there is a lot of individual variability. Consistently achieving appropriate and adequate attenuation is important. Even within a single individual, each time an earplug is re-inserted, its performance may be different. In the case of foam earplugs, this variability can range from 2 dB to over 6 dB (Wu et al. 2013). In this discussion, we refer to this measurement as the within-person re-fitting variability.

Industrial field studies.

Neitzel et al. (2006) conducted a study at a corrugated-product plant to assess performance of both foam (E-A-R Classic, NRR 31dB) and custom plugs (Custom Protect Ear, Surrey BC, 24 dB rating). The variability of repeated fittings on 20 people are shown in Table 1. Unfortunately, individual results were not presented. The custom-molded HPD had a 6 dB within-person refitting variability. When one extreme outlier (out of 20) who had a 30 dB difference between re-tests was removed, the variability decreased to 3 dB.

Type of Earplug	Within-Person Refitting Variability (SD)
Custom-molded (all people)	6 dB
Custom-molded (minus one outlier)	3 dB
Foam	5 dB

Table 1. Variability (standard deviations) in field measurements of earplugs (adapted from Neitzel et al. 2006). The variability reported here was measured with a Field Microphone-in-Real-Ear (F-MIRE) system, which is an accepted objective, acoustical measurement of sound level, despite differences from the REAT measurements used in other studies.

Tufts et al. (2012a) measured within-person re-fitting variability for custom earplugs (Phonak Serenity SP eShell). After individual training and practice, there was only a small variability in individuals re-fitting their plugs (standard deviation ~2.8 dB). Before training, that variability was slightly worse at 4.1 dB. The 3 dB variability is a good goal.

3. Effect of Training

As important as choosing effective HPDs in a hearing conservation program is, training is required to achieve the desired amount of attenuation, comfort, and the small variability of a person reinserting the HPD.

LCS Custom-Earplug User Training. Because custom earplugs are made to fit a specific ear, once an individual knows how to put a well-made custom plug into their ear, variability should be low (as seen in Table 1 and Tufts et al. 2012a). However, individuals must be instructed in wearing custom earplugs, as with any other type of earplug. Custom plugs are form-fitted to an individual wearer's ear and made of material that can be rigid, unlike standard-issue plugs, which are commonly made from foam or pliable plastic. Wearing them incorrectly could negatively affect attenuation and cause discomfort/irritation. Training for the LCS crews took place one-on-one; however, training in a small-group setting, would also be greatly advantageous.

User training with custom HPDs has not been studied in depth, but training has been reported to have a large effect on measured attenuation of foam earplugs. Joseph et al. (2007) showed that small group (2-6 people) or individual training provided an effective 11-15 dB improvement in attenuation over large-group (25 people) instruction with a population of college students. More recently, Murphy et al. (2011) repeated the study with a general population and found a 5-8 dB improvement. With the observed failure of foam-earplug use in the Fleet described in Bjorn et al. (2006), better foam insert training is clearly warranted; standard Navy training in earplug use and insertion is not sufficient. (Navy training is usually a PowerPoint or video to an entire group).

Figure 7 contains data acquired from LCS-1 crewmembers wearing foam earplugs, as they had been using for years. The fit-check system used was also the Michaels and Associates system. Each crewmember was tested to acquire a PAR with their own insertion technique (first attempt). Those with attenuation below 25dB (the attenuation chosen for this exercise) were instructed by a senior occupational audiologist on proper foam HPD preparation and insertion before the second attempt was made. Another round (third attempt) was performed if necessary (personal communication from T. Hutchison). The scatter is large, and many subjects fell below the target criterion attenuation on the first and second attempts. Many of the failures were due to poor fit by the sailor, as individual re-training from an experienced audiologist improved performance in most cases, even if repeated efforts were required. Other failures were due to inappropriate selection and/or size of HPD, and required a different HPD.

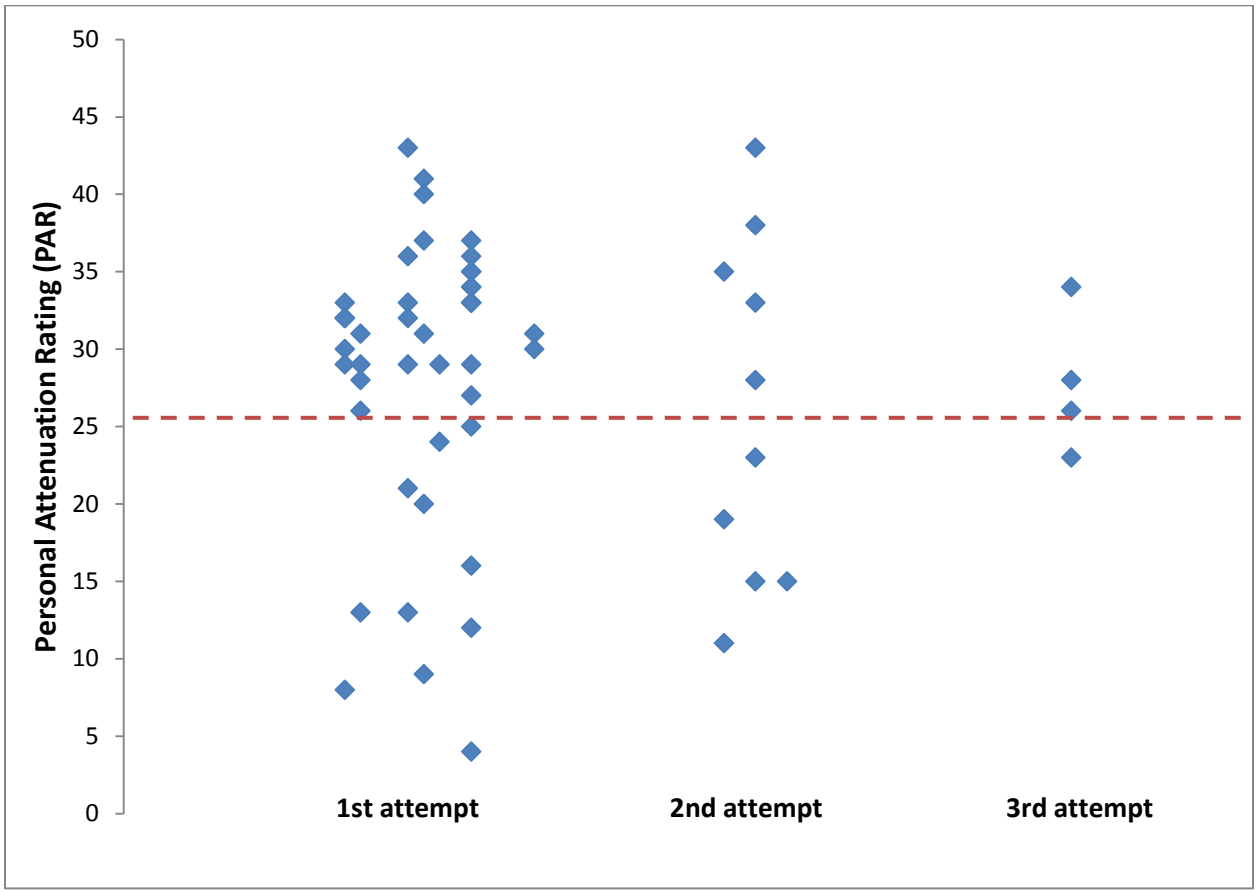

Figure 7. Attenuation measurements of foam earplugs in LCS-1 crewmembers. Each symbol is one ear.

4. Importance of comfort

Hearing protection is only effective when the user is wearing it correctly and consistently. Any reason for non-use, even for a short period of time, creates a hearing health hazard. Comfort is the most important factor for user acceptance of wearing HPDs (Davis 2008). In addition, users must be motivated to wear the HPD for the entire period in noise, frequently many hours.

LCS-1 Crew Attitude. Custom plugs were rated as wearable for longer (Figure 8) and more satisfactory overall compared to foam plugs (Figure 9) by the LCS-1 crew. The preference was overwhelming.

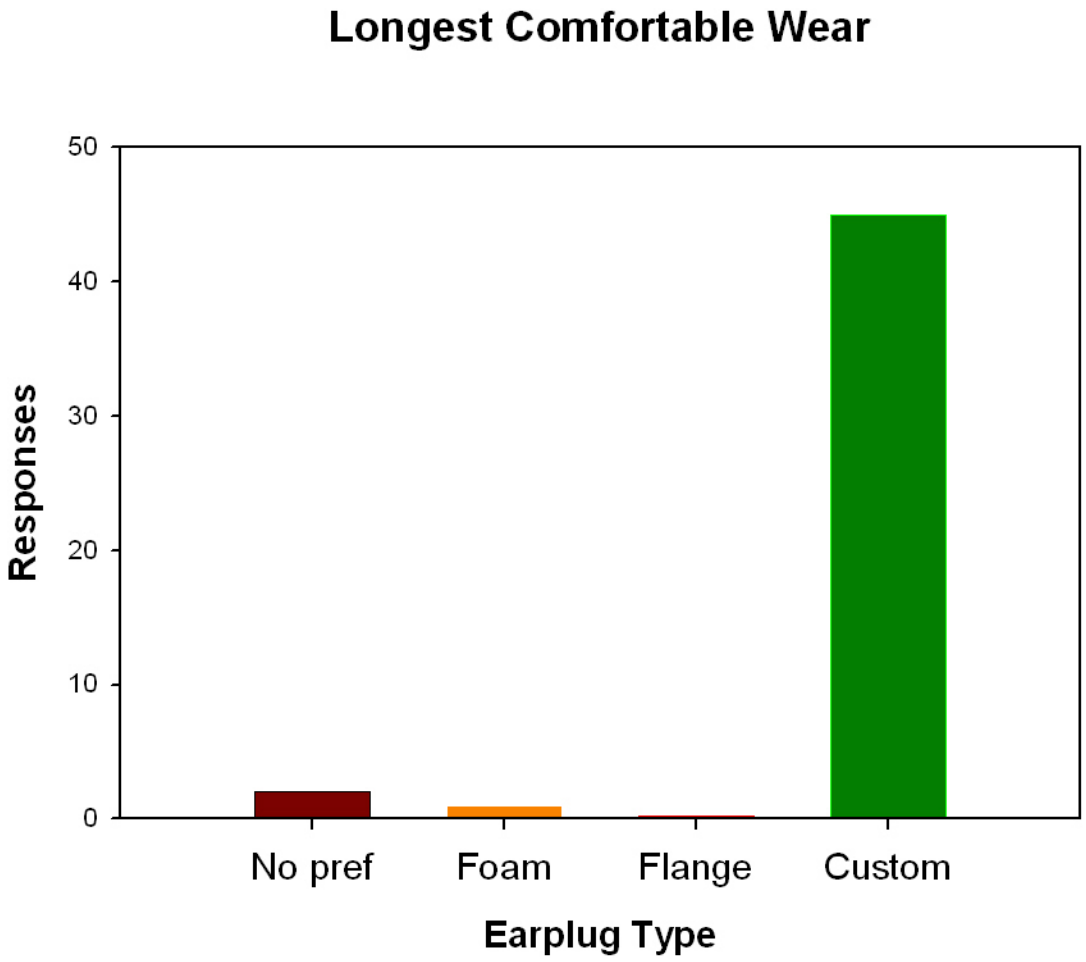

Figure 8. Compilation of crewmembers' reports of which earplug could be worn longest.

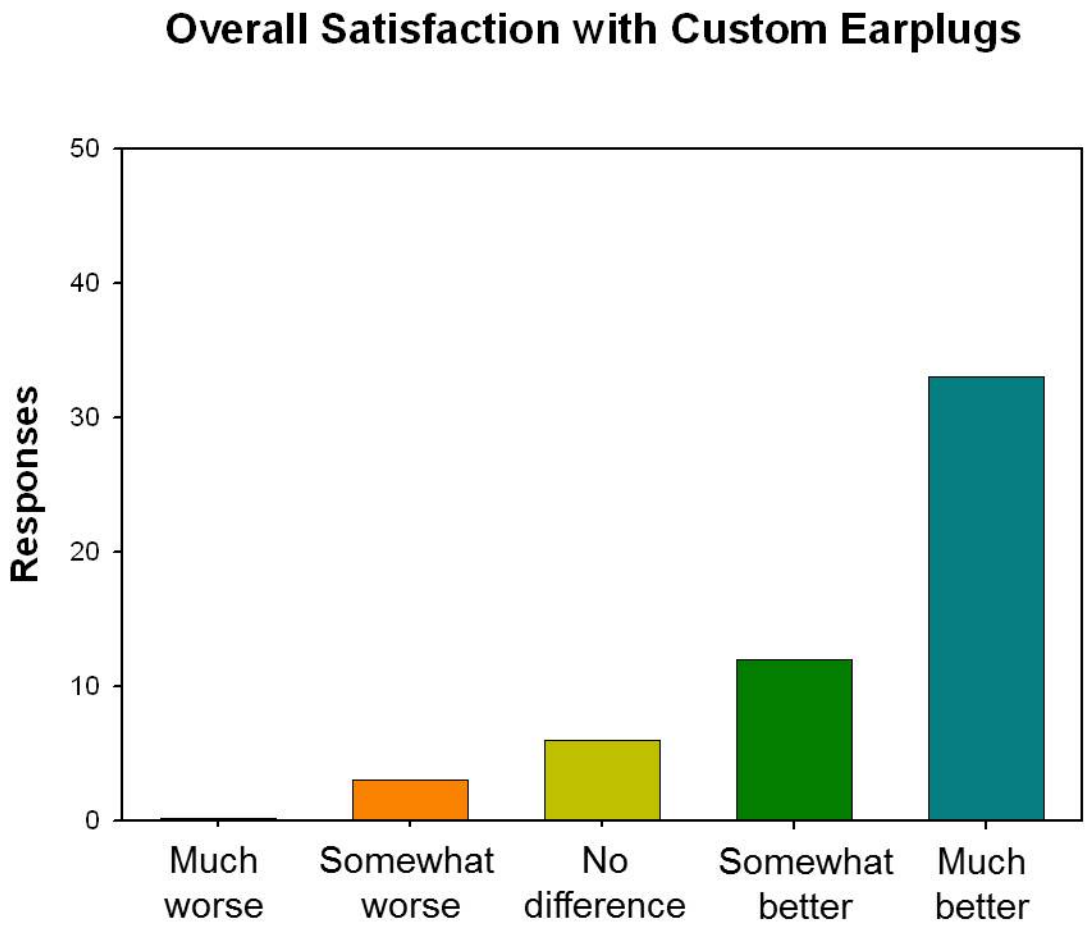

Figure 9. Compilation of crewmembers' answers to the question: "What is your overall satisfaction with your custom earplugs?"

The Neitzel et al. industry study cited previously also asked workers about HPD comfort. On a 5-point scale, foam was rated at 3.0, while the custom plugs received a higher 4.2 rating (Neitzel et al 2006). That positive difference bodes well for the workers to wear their custom plugs for a longer period of time.

Tufts' experiment on earplug shortening also included data on comfort. Two of the four individuals in that study did report discomfort at a specific depth and deeper. The smiley faces in Figure 6 indicate that discomfort existed for two subjects with plugs deeper than about 10 mm.

Deep-molded earplugs often do require an acclimatization period to achieve useful comfort, which was done with the LCS-1 crew; sailors reported taking an average of 6 days with a maximum of 60 days. Unfortunately, Tufts' study did not allow time for the subject to acclimate to each canal depth as it was changed daily. Therefore it is unknown if the two individuals reporting discomfort at the deepest depths would have benefited from a longer acclimatization.

Comfort may not be free; it may be at the cost of poorer attenuation. Byrne et al. (2011) tested 23 naïve subjects in one-hour sessions. A statistical analysis showed a significant tendency for less

comfortable foam earplugs to have higher noise attenuation. Thus maximum comfort should not be the goal; it should instead be "comfortable enough" for the necessary wearing time.

Both foam and custom earplugs work for many people. For some, it is not a matter of preference, but rather a matter of anatomy and/or physiology. For example, foam plugs are not available for those with much smaller- or much larger-than-average ear canals. One LCS-1 crewmember had very large ear canals, so the largest available foam plugs were too small to provide adequate protection. Another crewmember's small ear canals made it difficult to properly fit foam plugs. For both of these crew members, custom plugs were preferred over the foam plugs. A third LCS-1 crewmember could wear foam plugs for only about 10-15 minutes before developing an adverse reaction to them (e.g., he feels a "burning sensation" in his ears when wearing the plugs). Conversely, he was able to wear his custom plugs for as long as three hours without taking a break. Custom HPDs are not without their problems: another crewmember developed a severe skin problem that prevented his acclimatization to the custom earplugs.

Effect of partial wear. Use of HPDs for only part of a person's time in noise can be quite harmful. For example, consider an engine room with 104 dBA noise. A sailor stands 4-hour watches in these areas, and uses an earplug with 25 dB attenuation. When worn for the entire watch, the effective noise exposure is 79 dB, or below regulatory action levels. If due to discomfort, the sailor removes the HPD for just the last hour of each watch, the effective noise exposure is now 98 dB—definitely in the harmful range. If customs are worn longer than other HPDs as would be expected based on the crew survey above, then they would be more effective as a system solution.

5. Cost

Even if worn longer and are therefore more effective, are customs cost effective? Despite higher initial cost, the long-term cost to the Navy can be lower than foam earplugs, as Table 2 demonstrates.

The case in Table 2 has a baseline set of assumptions, as shown. Other reasonable assumptions are possible. Using more than one set of earplugs per watch would make the foam annual cost higher; retaining and re-using plugs at a later time would decrease the foam cost. Two watches a day is very common. The 140 days at sea is an average for an aircraft carrier over a multi-year cycle (Tufts et al. 2006). The LCS-1 has been used more intensely, with more time at sea, making the cost of foam higher. Most of these possibilities still show the custom plugs as less costly, but in any case, both types of HPDs have similar long-term cost. Therefore cost should not be a decisive factor in the decision to adopt custom plugs.

Only average purchase costs are compared - the greater disposal cost of over a thousand foam earplugs and the storage costs of the large volume of foam earplugs would make the comparison even weaker for the foam.

Earplug and Price	Initial Cost	Usage	Annual Cost
Foam Uncorded $0.24/pair Corded $0.53/pair	Average: $0.38	1 pair per watch x 2 watches per day x 140 days at sea = 280 pairs/sailor	$106.40
Custom High performance $68.42/pair Stereo ACCES $179.00/pair	$247.42	Assumes use of one purchase of plugs over 3 years.	$82.47

Table 2. Comparative cost of foam and the LCS-1 issue of two types of custom molded earplugs. Prices are as listed by the U.S. General Services Administration, and purchased for LCS-1, in 2012.

II. Conclusion and Recommendations

Custom-molded earplugs are a good addition to the Navy's efforts to preserve the hearing of its sailors and Marines. The acceptance of the plugs was high for an overwhelming majority of the LCS crewmembers, and the plugs are economical when their much longer, useful lifetime is considered. Noise attenuation is at least comparable to foam earplugs. Considering the probability of longer wearing periods, the overall effectiveness of custom HPDs should be higher than foam HPDs.

The following are our recommendations for improving the effectiveness of earplug usage.

Recommendation: Provide multiple types of HPDs, including custom earplugs.
Sailors who are allowed to make a personal choice of an earplug are more motivated to wear HPDs, and wear them for longer. However, not every sailor can wear custom-molded earplugs, nor can every sailor wear foam earplugs. Adverse reactions to the plug material and unusually shaped ear canals need to be accommodated. Multiple types of earplugs will continue to be needed to accommodate these restrictions as well as various noise environments for any effective effort to preserve hearing.

Recommendation: Improve Navy earplug training.
Training earplug users is known to positively impact earplug attenuation performance (Joseph et al, 2007; Murphy et al, 2011; Johnson and Calimlim, 2012). Properly fitted custom earplugs allow for consistency in attenuation when inserting because of the individual custom fit action. Some hands-on, individual training requirement still remains.

Recommendation: Check the attenuation of every earplug that is issued, including non-custom earplugs.
The variability in attenuation performance of earplugs across people is quite striking, even in nearly ideal laboratory settings. Field measurements show even more variability. The occasional "bad" plug seems able to pass visual inspection of experienced fitters. The best available solution is performance verification in the field (otherwise known as a fit check) when dispensing any HPD. This recommendation applies to foam as well as custom earplugs. Data from other LCS-1 crew on individual-fit of foam earplugs have shown that even with training, attenuation should be measured routinely.

Recommendation: Work toward goal of protection individualized to each sailor's exposure.
Custom earplugs have the capability to provide different amounts of attenuation – from moderate to large – by varying the depth of the canal piece. Maximal attenuation is important for some occupations, but for individuals who are in lower levels of noise intermittently throughout the day, maximal attenuation is not needed. Many types of earplugs can be "tuned" to best suit each person's job situation as mentioned previously. Individualized assessment of hearing-protection needs is an important part of a hearing-conservation program.

Recommendation: At a minimum, impression takers and earplug dispensers should attend a manufacturer's course, and receive refresher training from someone experienced in deep earmold impression taking and fitting.
No single preparation for an impression taker/manufacturer combination has yet shown to produce a consistently effective earplug. Nonetheless, all those who are making and dispensing custom HPDs must understand the importance of fit of the HPD in the ear canal, the importance of depth of the canal portion, the importance of "comfortable enough," and the importance of good training. These factors apply to all types of HPDs.

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